



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M355N .PdP

Food and Drug Administration
Atlanta District Office

19/27/97
HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

October 17, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Barbara R. Thomas, R.T.,(R),(N), CNMT
Associate Director
McLeod Regional Medical Center
Breast Imaging Department
555 East Cheves Street
Florence, SC 29506-2617

WARNING LETTER

Inspection ID: 1227700007

Dear Ms. Thomas:

Your facility was inspected on 10/1/97 by a representative of the South Carolina Department of Health and Environmental Control, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The interpreting physician did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]

The interpreting physician did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance that was listed on the inspection report provided to you at the close of the inspection. This level 2 noncompliance is:

No medical audit system to track positive mammograms was in place.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirement, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

U.S. Food and Drug Administration
Compliance Branch
60 8th Street, N.E.
Atlanta, Georgia 30309

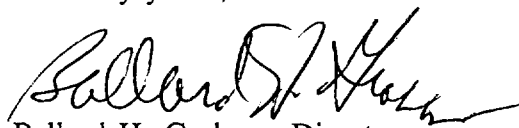
With a copy to:

South Carolina Department of Environmental Control (DHEC)
Bureau of Radiological Health
2600 Bull St.
Columbia, SC 29201

[NOTE: If phantom image is required for corrective action, please submit to S.C. Bureau of Radiological Health.]

You may choose to address both FDA and State requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call John J. McCall, Compliance Officer at (404) 347-3162.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director
Atlanta District

cc: HFI-35
JJM
HFA-224
HFC-210
HFZ-300
HFC-240
HFZ-306
HFZ-322
REK
TURNER
CLT-RP
FILE
LEGAL JKT.
HFA-244
HFC-230
HFZ-240
STATE AGENCY
HFZ-242
T. TROUT
C. FOULKS